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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,293	11/03/2003	Edward Nowak	3399-4006US1	6240

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EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
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1615

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06/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/701,293

Applicant(s)

NOWAK ET AL.

Examiner

Humera N. Sheikh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 10/030,902.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Receipt of the Response and Amendment after Non-Final Office Action, Applicant's Arguments/Remarks and the request for extension of time (2 months granted), all filed 03/19/07 is acknowledged.

Upon further consideration, the previous Non-Final Office Action filed 10/11/06 has been withdrawn. The following are the new grounds of rejection:

Claims 15-50 are pending in this action. Claim 1 has been cancelled herein. Claims 2-14 were previously cancelled. Claims 15-50 remain rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 15-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda *et al.* (EPO 0 211 079 A1) in view of Brown (WO 97/35537) and vice versa.

The instant invention is drawn to a delivery capsule having at least two separate chambers, the capsule including a dividing wall or septum defining in part two separate chambers, wherein the dividing wall or septum comprises two layers of material adhered together with an adhesive material.

Ueda *et al.* ('079) teach a soft multi-chamber delivery capsule, process of making and an apparatus for producing the capsule, wherein the capsule consists of a covering, the inner space of which is divided into a plurality of chambers by at least one partition. The number of such chambers is usually two, and the space between the first and second coverings is divided into two chambers by a partition provided therebetween. The capsule comprises a first, second and third film, whereby the films are joined under pressure, except their respective capsule-defining portions. The chambers contain materials, such as medicine, cosmetics or food (see Abstract).

Ueda teaches a soft capsule of novel structure, which, although single, is adapted to stably enclose at least two kinds of incompatible contents, and which can be made, for example, to have one portion of rapidly soluble or intragastrically soluble properties and the other portion of prolonged release or enteric properties, or to have one portion with a rapid release action and the other portion with a delayed release action. With the multicellular soft capsule, different contents can be enclosed in the different cells (page 2, lines 15-23).

Any material usually used for the shell of the soft capsules is usable for forming the shells and partition, such as gelatin, plasticizers, perfume, pigments, solubility, adjusting agents, etc. can be added as desired (pg. 11, lines 6-11).

The multicellular capsule may be of any shape, such as oval shape, oblong form, round form, tubular form or in the form of a suppository (pg. 11, lines 16-21).

The examples on pages 13-17 demonstrate the method of manufacturing the multicellular soft capsules.

It is noted that Ueda teaches a single film, whereas Applicants utilize two layers of material (adhered together with an adhesive material). However, it is the position of the Examiner that the soft capsules of Ueda entail a similar function and purpose as that of the instantly claimed delivery capsule. Ueda explicitly teaches a soft, divided, multi-compartmented capsule to hold various active substances that can be incompatible with each other. Moreover, Applicants have not demonstrated any significant patentable distinction between the Ueda delivery capsule and the instant delivery capsule. The Ueda capsule would be capable of imparting effective drug delivery to a user in need thereof.

Ueda *et al.* do not explicitly teach chambers containing metered doses of materials contained within the capsule.

Brown ('537) teaches capsules comprising metered doses of substances to be encapsulated within the capsule, carried out through injection, wherein as the doses of substances are injected between the heated films, the films deform to line the indentations, forming series of pairs of opposed capsule halves containing the substance (see page 6, lines 5-19).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the capsules of Brown within the teachings of Ueda, because Brown explicitly teaches capsules that can efficiently comprise metered doses of substances contained

within the capsule. The expected result would be an improved multicellular capsule comprising metered doses of varying substances for effective capsule delivery.

* * * * *

Brown ('537) discloses capsules, a method of encapsulation and an encapsulation apparatus, wherein the capsules comprise metered doses of substances to be encapsulated within the capsule, wherein as the doses of substances are injected between the heated films, the films deform to line the indentations, forming series of pairs of opposed capsule halves containing the substance. The pairs of capsule halves are then brought together, sealed and cut, thus forming capsules containing the substance.

The method of encapsulation is characterized by supplying to an encapsulation unit, two films of like material capable of deforming elastically at least when partially solvated, and applying solvent to at least one of the films prior to encapsulation to cause partial solvation of the material surface, such that the partially solvated surface can adhere to and seal with the film material. The invention enables encapsulation-using materials other than gelatin, such as polyvinyl alcohol. Further suitable materials include alginate, hydroxypropyl methyl cellulose and polyethylene oxide, for example (see page 6, lines 5-19 and Abstract).

Brown teaches a single chamber that is not divided. Brown does not teach two separate chambers having a dividing wall or partition.

Ueda ('079) teaches a soft multi-chamber delivery capsule, process of making and an apparatus for producing the capsule, wherein the capsule consists of a covering, the inner space of which is divided into a plurality of chambers by at least one partition. The number of such chambers is usually two, and the space between the first and second coverings is divided into two chambers by a partition provided therebetween. The capsule comprises a first, second and third film, whereby the films are joined under pressure, except their respective capsule-defining portions. The chambers contain materials, such as medicine, cosmetics or food (see Abstract).

Ueda teaches a soft capsule of novel structure, which, although single, is adapted to stably enclose at least two kinds of incompatible contents, and which can be made, for example, to have one portion of rapidly soluble or intragastrically soluble properties and the other portion of prolonged release or enteric properties, or to have one portion with a rapid release action and the other portion with a delayed release action. With the multicellular soft capsule, different contents can be enclosed in the different cells (page 2, lines 15-23).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate multi-compartments comprising a partition as taught by Ueda within the capsules of Brown. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Ueda teaches a soft multi-chamber delivery capsule containing a partition, whereby the multiple compartments function to hold at least two components or substances that can be incompatible with each other. The expected result would be an improved multi-compartmented capsule for delivering metered doses of varied active substances.

Response to Arguments

Applicant's arguments filed 3/19/07 have been fully considered and were found to be partially persuasive.

Applicant has overcome the following objection(s) and/or rejection(s) by virtue of the amendment and/or persuasive remarks: (1) The claim objection for claim 15 (duplicate claim) has been withdrawn by virtue of the cancellation of claim 1; (2) The 35 U.S.C. §102(b) rejection of claims 1 and 15-50 over Brown (WO 97/35537) has been withdrawn; and (3) The 35 U.S.C. §102(b) rejection of claims 15, 16, 19, 20, 28-29, 31, 35-36, 38, 42, 43, 47 and 49 over Ueda (EPO 0 211 079) has been withdrawn.

With regards to Brown ('537), Applicant argued, "Brown is generally directed to a method of encapsulation for forming capsules. The capsules are formed by bringing together two opposed capsule halves in the shape of open hemispheres, such that they form a **single, undivided** chamber. Nowhere is Brown seen to disclose or suggest a septum or a dividing wall of any kind, let alone a dividing wall or septum having two layers of material adhered together with an adhesive material."

Applicant's arguments were persuasive. The rejection has now been reformulated as Ueda ('079) in view of Brown and vice versa. While Brown do not teach a divided capsule having more than one compartment, the Ueda reference has been relied upon for the teaching of a soft divided capsule having multiple compartments to hold various active substances that can be incompatible with each other.

With regards to Ueda ('079), Applicant argued, "Ueda is directed to a multi-chamber capsule divided into a plurality of chambers, the chambers are divided by a **single** film. More particularly, Ueda teaches a system and method in which films are deformed into cavities in a rotating drum, such that the cavities are filled when the opening to these cavities are in a vertical or substantially vertical position. See Ueda, Figure 2; p.9 ll. 7-25. Alternatively, Ueda discloses filling one cavity when the cavity is in a horizontal position, applying a septum material to the top of this cavity, applying the second filling material to the top of the septum and then applying the second capsule cavity material on top of both the septum and the second filling material. See Ueda, p. 10, 1.17 -p. 11, 1.5. In both cases, the position of the cavities during filling is determined by Ueda's reliance on only a single septum material. This is entirely unlike the claimed invention, in which both capsule cavities can be filled when the entrance to the cavity is in the horizontal plane, with the use of septum materials for each cavity enabling the cavities to be sealed before these cavities are rotated. This provides a

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far more simple and efficient filling process. In addition, this enables the cavities to be only partially filled (in contrast to Ueda and Brown, which both rely on the filling process to deform the film and create the cavities), allowing the capsules to have greater propensity for distortion of shape (e.g., "softness") such that, for example, the capsules may be more easily swallowed. Further, given the importance of the provisions of metered doses, the greater efficiency in the filling of the capsules via the claimed methods are clearly of greater advantage. Moreover, there are technical reasons as to why one of ordinary skill in the art, reading Ueda, would not contemplate the use of adhesive, even to apply the single septum material disclosed therein to both sides of the capsule. As disclosed on page 9, lines 13-18 of Ueda, the three films must be compressed together prior to the filling of the capsules. This is because of the vertical nature of capsule filling in Ueda, as otherwise the filling material would simply not be caught by the capsules. If instead of compression, adhesive was relied upon to seal the films, it would be necessary to allow the adhesive to set prior to applying the filling material. This would significantly slow the process or production of Ueda, such that it would not be contemplated by one of ordinary skill in the art. This is particularly so, given that Ueda teaches that compression is an adequate form of sealing, removing any motivation to contemplate the use of adhesive as a sealing means. Accordingly, Brown and Ueda, whether taken alone or in combination, are not seen to disclose or suggest the features of independent Claims 15, 46 and 47, particularly with respect to at least the features of (i) a dividing wall or a septum having two layers of material adhered together with an adhesive material and (ii) supplying a respective film of a dividing septum material to each of two filled capsule portions."

Applicant's arguments were not persuasive. Applicant's argument that "In both cases, the position of the cavities (vertical and horizontal) during filling is determined by Ueda's reliance on only a single septum material was not persuasive since Applicant has not established any significant patentable distinction, which accrues from the use of a two-layered film as a septum material. The capsule of Ueda functions in a similar manner to the capsule of the instant invention. The Ueda capsule is comprised of multiple compartments to hold different active substances. Applicant's argument that "the instant invention allows greater propensity for distortion of shape (e.g. softness) was not persuasive since the capsule of Ueda is a soft capsule which would also be easy to swallow. The argument that 'Ueda uses compression, rather than adhesive as a means for sealing' was not persuasive since the fact that Applicant uses an adhesion means for sealing purposes does not deter one of ordinary skill in the art from using the teachings of Ueda, who explicitly teaches a multi-compartmented capsule capable of holding various active substances that may be incompatible with each other. As noted above, the Ueda capsule functions in a similar manner and purpose as that of the instantly claimed capsule.

Absent any evidence or showing of unexpected results demonstrated by the instant invention, the teachings of the combined references meet the claim limitations of the instant invention.

Conclusion

--No claims are allowed at this time.

Correspondence


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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June 06, 2007


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PRIMARY EXAMINER
70-1600